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09/931,729	08/16/2001	Juan Ygucrabide	089498-0314	5423

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/931,729	YGUERABIDE ET AL.
	Examiner	Art Unit
	Ann Y. Lam	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *115-161* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *115-161* is/are rejected.

7)☒ Claim(s) *148-161* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed March 8, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. (Examiner cannot locate the copies of the non-patent literature. Examiner requests that Applicant submit or re-submit the non-patent literature in the IDS.)

Election/Restrictions

In view of the amendments to the claims, the restriction requirement in the previous Office action is hereby withdrawn.

Specification

The disclosure is objected to because of the following informalities: the brief description of the drawings do not include figures 5c and 15a and 15b (a description of "figure 15" is not sufficient.)

Appropriate correction is required.

Claim Objections

Claims 148-161 are objected to because of the following informalities: in claim 148, line 6, "wherein" should be deleted because of redundancy. Claim 115, line 10, after "light", --source—should be added. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 116, 120, 137-142 and 148-161 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 116 is vague and indefinite since it is not clear as to whether or not the "sample device" is claimed as part of the apparatus. (In claim 116, line 1, "wherein" should be –further comprising--.)

Regarding claim 120, the phrase "other well-containing device" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "other well-containing device"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). (The term "other" should be deleted.)

Claims 137-142 recite the limitation "each separate area", or depends from a claim that recites "each separate area". However, there is insufficient antecedent basis for this limitation in the claim. (Claim 136, line 2, --having a plurality of separate areas—

should be added after "microarray", in order to provide the proper antecedent basis for claims 137-142.)

Claims 139 and 140 recite the limitation "the number of particles", in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 148 and thus its dependent claims 149-161, are vague and indefinite since claim 148, lines 6 and 7 recite the limitation "particles". There is insufficient antecedent basis for this limitation in the claim.

Claim 151 recites the limitation "wherein...light from said light source illuminates said sample after passing through the sample device". However, claim 151 depends from claim 150, and claim 150 recites "wherein...light from said light source illuminates said sample without first passing through the sample device". Thus, claim 151 is vague and indefinite since light from the light source cannot illuminate a sample both after passing through a sample device and also without first passing through the sample device.

Claims 159, and thus its dependent claim 160, are vague and indefinite since it is not clear in claim 159 whether or not "a high refractive index medium" is claimed as part of the apparatus. (It appears that "wherein" in line 1 of claim 160, should be replaced by –further comprising--.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 115, 117, 122-124, 129, 131, 135-138, 142, 148-150, 153, 154 and 158-159 are rejected under 35 U.S.C. 102(b) as being anticipated by Swope et al., 5,350,697.

As to claim 115, Swope discloses an apparatus for analysis of a sample on a solid phase surface, comprising:

a light source (1) oriented to deliver light to a sample on a solid phase surface (4) without the light first passing through said solid phase surface; and

a scattered light detector (5) located such that said detector is on a same side of said solid phase surface as said light source (see figure 1),

wherein said apparatus is configured such that light scattering particles associated with said sample are illuminated by said light under conditions that produce scattered light from said particles and said scattered light is detectable by a human eye with less than 500 times magnification and without electronic amplification (col. 3, lines 46-48.) (This limitation relates to intended use. The apparatus is capable of producing scattered light from the particles detectable by a human eye with less than 500 times magnification, depending on use of visible wavelength produced by the laser and depending on the particle size for example.)

As to claim 117, the device comprises a sample device holder (2) for positioning a sample device (4) within the apparatus (see figure 1; sample device holder 2 is considered to be adapted to hold sample device 4 since it is connected to it);

As to claim 122, the apparatus further comprises a light guide (i.e., prism, col. 3, line 54) for the illuminating light.

As to claim 123, the light guide is a prism (col. 3, line 54.)

As to claim 124, the apparatus further comprises one or more lenses (col. 3, line 54) through which illuminating light passes, for collecting or focusing or both.

As to claim 129, the apparatus further comprises an electronic detector (5) for detecting scattered light (col. 5, line 23.)

As to claim 131, said light source laser diode (col. 3, line 53.)

As to claim 135, the apparatus further comprises a photdetector, comprising a still camera or video camera (col. 5, line 16) to detect said scattered light.

As to claims 136-138, the apparatus is configured for conducting an assay of a microarray, wherein each separate area of the microarray has a dimension between ten square microns and one square millimeter, or a dimension greater than one square millimeter (col. 5, lines 37-41.) The apparatus is configured for conducting an assay of a microarray since it is capable of conducting an assay of a microarray (col. 5, lines 37-41.)

As to claim 142, the apparatus is configured to detect the light intensity of each separate areas (col. 4, line 36.)

As to claim 148, Swope discloses an apparatus comprising:

a sample device holder (2) adapted to hold a sample device (4) bearing a sample for analysis (see figure 1; sample device holder 2 is considered to be adapted to hold sample device 4 since it is connected to it);

a light source (1) oriented to illuminate the sample with non-evanescent wave light when the sample device is present in the sample device holder (col. 3, lines 46-48); and

a scattered light detector (5) cooperating with said sample device holder and said illumination system to detect light scattered from particles in the sample (col. 3, lines 6-10),

wherein the light scattered from the particles in the sample is detectable by a human eye with less than 500 times magnification and without electronic amplification.

As to claim 149, the light source (1) and detector (5) are on a same side of the sample device (see figure 1.)

As to claim 150, light from the light source illuminates the sample without first passing through the sample device (4), (see figure 1.)

As to claim 153, the sample device is a cuvette (col. 4, line 61.)

As to claim 154, the sample device comprises a solid-phase surface for bearing the sample for analysis (col. 4, line 61.)

As to claim 158, said detector further comprises a video or still camera (col. 5, line 16.)

As to claim 159, the apparatus further comprise the sample device (4.)

2. Claims 115, 117-121, 124-131, 136-138, 141, 143-147 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicoli et al., 4,647,544.

As to claim 115, Nicoli discloses an apparatus for analysis of a sample on a solid phase surface, comprising:

a light source (32) oriented to deliver light to a sample on a solid phase surface (10, or alternatively 42) without the light first passing through said solid phase surface (see figure 1 and figure 2c); and

a scattered light detector (30) located such that said detector is on a same side (see figure 1) of said solid phase surface as said light source,

wherein said apparatus is configured such that light scattering particles associated with said sample are illuminated by said light under conditions that produce scattered light from said particles and said scattered light is detectable by a human eye with less than 500 times magnification and without electronic amplification (see col. 11, lines 11-14, disclosing lasers producing visible wavelengths.) (This limitation is related to intended use. The particles produce scattered light that is detectable by a human eye with less than 500 times magnification, depending on the particle size for example.)

As to claim 117, the apparatus further comprises a sample device holder (40, non-grooved portions) for positioning a sample device (42, the grooves in 40) within the apparatus, wherein the sample device comprises the solid phase surface (see figure 4a.)

As to claim 118, the apparatus further comprises the sample device (42.)

As to claim 119, said sample device is an array slide, or array chip or array plate (col. 7, lines 38-41, disclosing a surface (10), considered to be a slide or plate, and having an array 12 of antibodies.)

As to claim 120, the sample device is a well-containing device (40, see figure 4a.)

As to claim 121, a high refractive index medium (i.e., solvent, col. 5, line 67) is introduced at said solid phase surface, thereby increasing the refractive index of the medium surrounding said light scattering particles. The antigens (col. 5, line 67) are considered the claimed "particles", and the solvent (col. 5, line 670) in the liquid sample is considered the claimed "high refractive index medium". Examiner notes that the term "high" is relative, and Applicant has not recited limitations that overcome Nicoli.

As to claim 124, the apparatus further comprises one or more lenses through which illuminating light passes, for collecting or focusing or both (col. 21, lines 65-68, disclosing a lens to collect scattered light.)

As to claim 125, the apparatus further comprises a collection lens to collect said scattered light for directing said scattered light detector (col. 21, lines 65-68, disclosing a lens to collect scattered light.)

As to claim 126, the apparatus further comprises one or more lenses to provide a focused image of the sample (col. 21, line 65 – col. 22, line15, disclosing a lens to collect scattered light, to provide a patterned image of the sample.)

As to claim 127, the apparatus further comprises at least one optical filter, arranged such that illuminating light, or scattered light, or both pass through it (col. 16, lines 35-36, disclosing a bandpass filter in front of the detector.)

As to claim 128, said optical filter is a narrow band pass filter (col. 16, lines 35-36.)

As to claim 129, the apparatus further comprises an electronic detector for detecting scattered light (col. 9, lines 15-17.)

As to claim 130, the apparatus further comprises an image processor that discriminates light scattering signals based on intensity (col. 9, lines 50-54.)

As to claim 131, said light source is a laser diode (col. 7, line 59.)

As to claim 136, the apparatus is configured for conducting an assay of a microarray (col. 6, lines 5-10.)

As to claim 137, each separate area of the microarray has a dimension between ten square microns and one square millimeter (col. 11, lines 19 and 27, disclosing an array of 10 microns; see also, col. 11, lines 55-58.) Examiner notes that Applicant has not defined what "each separate area" encompasses.

As to claim 138, each separate area of the microarray has a dimension greater than one square millimeter. (Applicant does not positively recite the microarray in claim 138. Thus, the Nicoli apparatus meets the claims since it is capable of conducting an assay of a microarray of the claimed range of dimensions in claim 138. Moreover, since it is not clear as to what Applicant is referring in the limitation "microarray" (i.e., microarray of antibodies, or microarray of structural features on the surface 10), for

examination purposes, the microarray refers to etiher a microarray of antibodies or a microarray of structural features on a surface. Furthermore, Examiner emphasizes that Applicant has not defined what encompasses "each separate area", and thus, for purposes of examination, any two areas on a microarray is considered "each separate area".

As to claim 141, the apparatus is configured to detect the light intensity in each of the separate areas (col. 22, lines 43-47.)

As to claim 143, the apparatus is configured to detect and distinguish a plurality of different particles by a characteristic of the light scattered by the particles (col. 22, lines 43-47, disclosing detection of binding of molecules, wherein the molecules are considered the claimed "particles".) (Alternatively, col. 15, lines 5-9, and line 25, discloses metallic ions, or colloidal gold particles attached to antigens or antibodies, to increase scattering efficiency. The metallic ions or colloidal gold particles are considered the claimed "particles".)

As to claim 144, the apparatus distinguishes different particles by color of the scattered light (col. 6, lines 35-36, disclosing source of radiation having wavelength in the visible region; and col. 9, lines 14-17, disclosing photodiode to detect the wavelength.) Examiner notes that Applicant has not claimed from what the different particles are distinguished.

As to claim 145, the apparatus distinguishes different particles by intensity of the scattered light (col. 6, lines 21-25.)

As to claim 146, the apparatus distinguishes different particles by peak light scattering wavelength of the scattered light (col. 23, lines 4-8, and col. 9, lines 10-15.)

As to claim 147, the apparatus comprises a plurality of different bandpass filters (col. 16, lines 35-36) capable of providing separate detection of light scattered from different particle types.

3. Claims 115-118, 129, 131-133, 136-143, 145, 148-151, 153, 154, 159-161 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottingham, 4,597,944.

As to claim 115, Cottingham discloses an apparatus for analysis of a sample on a solid phase surface, comprising:

a light source (26) oriented to deliver light to a sample on a solid phase surface (23) without the light first passing through said solid phase surface; and

a scattered light detector (27) located such that said detector is on a same side of said solid phase surface as said light source (see figure 5),

wherein said apparatus is configured such that light scattering particles associated with said sample are illuminated by said light under conditions that produce scattered light from said particles and said scattered light is detectable by a human eye with less than 500 times magnification and without electronic amplification (col. 4, lines 46-48, disclosing a light emitting diode for directing monochromatic light toward a sample slide.) (This limitation is related to an intended use. The light emitting diode is capable of producing light in the visible spectrum directed towards the particles

scattering light detectable by a human eye with less than 500 times magnification, depending on the particle size for example.)

As to claim 116, a sample device comprises said solid phase surface (23) and said detector (27) is substantially perpendicular to said solid phase surface (see figure 5.)

As to claim 117, the apparatus further comprises a sample device holder (21) for positioning a sample device (23) within said apparatus (col. 4, lines 57-59), wherein the sample device comprises said solid phase surface (23.)

As to claim 118, the apparatus further comprises said sample device (23.)

As to claim 129, the apparatus further comprises an electronic detector (27, see col. 7, lines 44-48) for detecting scattered light.

As to claim 131, said light source is light emitting diode (LED), (26, see col. 4, line 60.)

As to claim 132, the apparatus further comprises a particle counter comprising computer software or firmware (63) to detect said scattered light and count the number of light scattering particles in selected areas (col. 6, lines 63-65; and col. 7, line 66 – col. 8, line 16.)

As to claims 133, 141-143, and 145, the apparatus further comprises an integrated light intensity detector comprising software or firmware (69, see col. 7, lines 44-48, and col. 8, lines 13-16) configured to detect said scattered light

As to claim 136, the apparatus is configured for conducting an assay of a microarray since it is capable of conducting an assay of a microarray (col. 9, lines 1-2.)

Examiner notes that Applicant has not defined what the microarray comprises. For examination purposes, Examiner considers that the microarray comprises a microarray of analytes of interest or alternatively, the particles.

As to claims 137 and 138, the apparatus is configured for conducting an assay of a microarray wherein each separate area of the microarray has a dimension between ten square microns and one square millimeter, or greater than one square millimeter, since it is capable of conducting an assay of a microarray having those dimensions (col. 9, lines 1-2.)

As to claim 139, the apparatus is capable of detecting the number of particles in each of the separate areas (col. 6, lines 50-51.) Examiner notes that Applicant has not define what the separate areas comprise. For examination purposes, Examiner considers any separate area of a microarray to be the claimed "separate areas".

As to claim 140, the apparatus is capable of detecting the number of particles in each of the separate areas (col. 6, lines 50-51.)

As to claim 148, Cottingham discloses an apparatus comprising:

a sample device holder (21) adapted to hold a sample device (23) bearing a sample for analysis;

a light source (26) oriented to illuminate the sample with non-evanescent wave light when the sample device is present in the sample device holder; and

a scattered light detector (27) cooperating with said sample device holder and said illumination system to detect light scattered from particles in the sample,

wherein the light scattered from the particles in the sample is detectable by a human eye with less than 500 times magnification and without electronic amplification (col. 6, lines 28-30.)

As to claim 149, the light source (26) and detector (27) are on a same side of the sample device (see figure 5.)

As to claim 150, light from the light source illuminates the sample without first passing through the sample device (see figure 5.)

As to claim 151, light from the light source illuminates the sample after passing through the sample device (see figure 5.)

As to claim 153, the sample device (23) is a slide (col. 4, line 58.)

As to claim 154, the sample device (23) comprises a solid-phase surface for bearing the sample for analysis (col. 4, line 58.)

As to claim 159, the apparatus further comprise the sample device (23.)

As to claim 160, a high refractive index medium (i.e., fluid from the sample) is disposed on the sample device, thereby increasing the refractive index of the medium surrounding the light scattering particles (i.e., analyte.) The analyte (e.g., penicillin, col. 3, line 37) is considered the claimed "particle", and the fluid in the sample (e.g., milk, col. 3, line 37) is considered the claimed "high refractive index medium". Examiner notes that the term "high" is relative, and Applicant has not recited limitations that overcome Cottingham.

As to claim 161, the detector is oriented to detect light scattered substantially perpendicular to the sample device (see figure 5.)

4. Claims 115-118, 122, 124-126, 129-134, 143, 148, 152-154, 159 and 160 are rejected under 35 U.S.C. 102(b) as being anticipated by Ford, Jr., 5,305,073.

As to claim 115, Ford discloses an apparatus for analysis of a sample on a solid phase surface, comprising:

a light source (col. 6, line 18) oriented to deliver light to a sample on a solid phase surface (10) without the light first passing through said solid phase surface (see figure 1 and figure 2); and

a scattered light detector (62) located such that said detector is on a same side of said solid phase surface as said light source (col. 6, lines 18-24, and col. 4, lines 4-6, and figure 2),

wherein said apparatus is configured such that light scattering particles associated with said sample are illuminated by said light under conditions that produce scattered light from said particles and said scattered light is detectable by a human eye with less than 500 times magnification and without electronic amplification (col. 4, lines 56-58, disclosing a laser having an output wavelength in the range of about 400 nanometers to 900 nanometers, i.e., including wavelengths in the visible spectrum.) (This limitation relates to intended use. The light scattered by the particles is detectable by a human eye with less than 500 times magnification, depending on particle size, for example.)

As to claim 116, a sample device (10) comprises said solid phase surface and said detector (62) is substantially perpendicular to said solid phase surface (col. 6, lines 18-24 and col. 4, lines 4-6, and figure 2.)

As to claim 117, the apparatus further comprises a sample device holder (92) for positioning a sample device (10) within said apparatus, wherein the sample device comprises said solid phase surface (col. 6, line 52.)

As to claim 118, the apparatus further comprises said sample device (10.)

As to claim 122, the apparatus further comprises a light guide (60) for the illuminating light (col. 6, lines 24-25.)

As to claim 124, the apparatus comprises one or more lenses (60) through which illuminating light passes, for collecting or focusing or both (col. 6, lines 24-25.)

As to claim 125, the apparatus comprises a collection lens (60) to collect said scattered light for directing said scattered light detector (col. 6, lines 24-25.)

As to claim 126, the apparatus further comprises one or more lenses (60) to provide a focused image of the sample.

As to claim 129, the apparatus further comprises an electronic detector (44) for detecting scattered light (col. 5, lines 55-56.)

As to claim 130, the apparatus further comprises an image processor that discriminates light scattering signals based on color or intensity (col. 5, line 59) or both.

As to claim 131, said light source (col. 6, line 18) is a laser diode (col. 4, line 50.)

As to claim 132, the apparatus further comprises a particle counter (80 and 130, col. 6, line 41, and col. 7, line 9) comprising computer software or firmware (130, col., 7,

line 9) to detect said scattered light and count the number of light scattering particles in selected areas.

As to claim 133, the apparatus further comprises an integrated light intensity detector (44 and 130, col. 5, lines 55-59, col. 12, lines 21-24) comprising software or firmware (col. 12, lines 21-24) to detect said scattered light.

As to claim 134, the apparatus further comprises an integrated light intensity detector (44 and 130) and a particle counter (80 and 130), comprising computer software or firmware to detect said scattered light.

As to claim 143, the apparatus is configured to detect and distinguish a plurality of different particles by a characteristic (i.e., intensity, col. 12, lines 21-24) of the light scattered by the particles. Examiner notes that Applicant has not claimed from what the different particles are distinguished.

As to claim 148, Ford discloses an apparatus comprising:

a sample device holder (92) adapted to hold a sample device (10) bearing a sample for analysis (see col. 6, line 52 and figure 4);

a light source (20) oriented to illuminate the sample with non-evanescent wave light when the sample device is present in the sample device holder (col. 4, lines 50-58); and

a scattered light detector (44) cooperating with said sample device holder and said illumination system to detect light scattered from particles in the sample (col. 5, lines 51-55, and figure 1),

wherein the light scattered from the particles in the sample is detectable by a human eye with less than 500 times magnification and without electronic amplification (col. 4, lines 56-57.)

As to claim 152, the light source (20) and scattered light detector (44) are positioned on opposite sides of the sample device (10), (see figure 1.)

As to claim 153, the sample device (10) is a flow cell (col. 4, line 37.)

As to claim 154, the sample device (10) comprises a solid-phase surface for bearing the sample for analysis (col. 4, line 37.)

As to claim 159, the apparatus further comprise the sample device (10.)

As to claim 160, a high refractive index medium (i.e., solvent, col. 4, line 40) is disposed on the sample device, thereby increasing the refractive index of the medium surrounding the light scattering particles. The molecules of interest (col. 4, line 41) are considered the claimed "particles", and the solvent (col. 4, line 40) in the liquid sample is considered the claimed "high refractive index medium". Examiner notes that the term "high" is relative, and Applicant has not recited limitations that overcome Ford.

5. Claims 148, 155-157 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer, 4,210,384.

As to claim 148, Meyer discloses an apparatus comprising:

a sample device holder (6) adapted to hold a sample device bearing a sample for analysis;

a light source (9) oriented to illuminate the sample with non-evanescent wave light when the sample device is present in the sample device holder; and

a scattered light detector (26) cooperating with said sample device holder and said illumination system to detect light scattered from particles in the sample,

wherein the light scattered from the particles in the sample is detectable by a human eye with less than 500 times magnification and without electronic amplification . (This limitation is related to intended use. Scattered light from particles are detectable by a human eye with less than 500 times magnification depending on particle size for example.)

As to claim 155, the detector comprises collection optics (e.g., objective lenses, col. 3, lines 67) for collecting and magnifying the scattered light .

As to claim 156, the collection optics produce a scattered light image viewable by a human eye (col. 3, lines 67.)

As to claim 157, the detector further comprises a video camera (col. 3, lines 46-49, and 54-55.)

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Craig et al., 4,480,042, discloses high refractive index polymers to enhance light scattering assays. Related patents: Yguerabide et al., 6,214,560, and Yguerabide et al., 6,586,193.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/10/04